K 041335

510(k) SUMMARY

JUN 1 6 2004

NAME AND ADDRESS: DENTSPLY International
World Headquarters
221 West Philadelphia Street
York, PA 17405
Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: May 18, 2004

TRADE NAME: PTM™ SYSTEM

CLASSIFICATION NAME: Porcelain Powder for Clinical Use (872.6660)

PREDICATE DEVICES: Finesse® Porcelain System K940252

DEVICE DESCRIPTION: The PTM™ SYSTEM is a press to metal system that consists of dental ceramic veneering materials designed for use in fixed prosthodontics devices that include both anterior and posterior crowns/bridges.

The PTM™ SYSTEM consists of an Opaque porcelain, Dentin/Enamel translucent ingots, Enamel Effect Porcelains, and a Glaze/Stain porcelain.

INTENDED USE: The PTM™ SYSTEM is used to veneer metal substructures for fixed prosthodontics.

TECHNOLOGICAL CHARACTERISTICS: The PTM™ SYSTEM represents a modification to the Finesse® Porcelain System. Changes have been made in the device's formulation and processing technique.

All of the components have been used in legally marketed devices. The formulations have not been changed in ways that may adversely impact safety or efficacy.

We believe that the prior use of the components in legally marketed devices, the similarity in the formulations between the modified device and the marketed device, and the data provided regarding the modifications to the marketed device support the safety and effectiveness of the PTM™ SYSTEM for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 6 2004

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

Re: K041335
Trade/Device Name: PTM™ System
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 18, 2004
Received: May 18, 2004

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K 041335

Device Name: **PTM™ SYSTEM**

Indications for Use:

Used to veneer metal substructures for fixed prosthodontics

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041335